REMARKS

This amendment is being filed in response to the Office Action dated October 15, 2007. For the following reasons, this application should be considered in condition for allowance and the case passed to issue.

Claims 10 and 11 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. It is stated that the term "a controllable device" is not defined explicitly in the specification or implicitly through its usage. Applicant has amended claims 10 and 11 to make clear that the controllable device is a pressure application device for applying pressure to the primary infusion line. However, it should not be considered new matter since claim 10 as originally drafted describes the controllable device for applying pressure from the primary infusion line. Hence, it would be clear to one of ordinary skill in the art that the controllable device is a device that can be controlled to apply pressure to the primary infusion line. The claims should be definite such that the rejection of claims 10 and 11 under 35 U.S.C. §112, second paragraph should be reconsidered and withdrawn.

Claims 1-19 were rejected under 35 U.S.C. §103(a) as being unpatentable over Butterfield et al. (hereinafter "Butterfield" in view of Fairchild et al. hereinafter "Fairchild") and further in view of Doan. This rejection is hereby traversed and reconsideration and withdrawal thereof are respectfully requested. The following is a comparison of the present invention as currently claimed with the applied references.

As provided in claim 1, for example, embodiments of the invention provide a system for determining a fault condition in an infusion system providing a primary infusion and a secondary infusion. The infusion system includes an infusion pump capable of infusing fluid from a

primary container connected to a primary infusion line and a secondary container connected to the primary infusion line through a secondary infusion line. The secondary infusion line has a valve to control a flow of the secondary fluid in the secondary fluid line. The primary infusion line has a check valve disposed between the primary container and the connection of the secondary infusion line to the primary infusion line. This check valve prevents the flow backwards from the primary infusion line into the primary container. The pressure sensor is disposed adjacent to primary infusion line below the connection of the secondary infusion line to the primary line. The pressure sensor is an operative arrangement with a primary infusion line to measure pressure within the primary infusion line. The pressure sensor provides signals representative of the pressure within the primary infusion line. A memory stores pressure related values. A processor is provided in communication with the memory and is responsive to the signals provided by the pressure sensor to determine the status of the primary infusion and the secondary infusion. The processor is programmed to sample the pressure signals, establish a baseline pressure value, store the baseline pressure value in the memory, compare the baseline pressure value with pressure values sampled at a latter time, and that the latter sample pressure value equals or is greater than the selected threshold pressure value, provide an alert that a fault condition exists.

None of the references, either alone or in combination, show or suggest the invention as now claimed. In particular, none of the references show or suggest a system for determining status in an infusion system that has a secondary infusion capability.

Butterfield, U.S. Patent No. 6,213,972 describes a fluid flow resistance monitoring system. The Examiner has stated that Butterfield only discloses a single source of intravenous fluid and does not directly disclose a secondary container connected to the primary infusion line

to a secondary infusion line. Thus, the Examiner has not shown that Butterfield provides any suggestion or showing of determining the status of a secondary infusion in a system that has a primary infusion and a secondary infusion. Nor has the Examiner described how the Butterfield reference would determine the status of a secondary infusion.

Fairchild, U.S. Patent No. 5,032,112, relates to a dual source intravenous administration set having an intravenous pump. There is no description regarding the determination of the status in such a system. Also, the Examiner describes Fairchild as teaching a controllable device 54 for applying pressure to the primary infusion line. However, this appears to be an error, since segment 54 is merely described as a third tubing segment and not a controllable device for applying pressure to a primary infusion line.

The Examiner considers it obvious to one of ordinary skill in the art to modify the device of Butterfield with the dual fluid container as taught by Fairchild for infusing more than one fluid. However, it is respectfully submitted that merely combining Fairchild with Butterfield would not modify the system for determining a fault condition in the now combined infusion system providing a primary infusion and a secondary infusion. The Examiner has not shown that Butterfield contemplates determining a status of a primary infusion and a secondary infusion, nor how such a determination of status of a primary infusion and a secondary infusion could be accomplished. It is apparent that the Examiner recognizes that a system having only a single infusion source is different from one having a primary infusion and a secondary infusion, by the citation of Fairchild. The current application describes the need for determining the status of a secondary infusion and discloses a system for doing so. The Examiner has not pointed out any description or suggestion in either Fairchild or Butterfield as to the desirability or the methodology for determining the status of a secondary infusion.

For all of these reasons, it is respectfully submitted that a prima facie case of obviousness has not been made out by the Examiner regarding claim 1 and those claims dependent therefrom. Further, claim 8 has also been amended similarly to claim 1, so that claims 8-11 should be considered allowable for the same reasons as claim 1.

Independent claims 12 and 16 both recite methods for determining whether a valve in a secondary infusion line is opened during a secondary infusion, or determining the status of a secondary infusion. Neither one of these methods is shown or suggested by either Fairchild or Butterfield, either alone or in combination, for the reasons stated above with respect to claims 1 and 8. Reconsideration and withdrawal of the rejection of these claims and those dependent from claims 12 and 16 are respectfully requested.

Doan, U.S. Patent No. 5,087,245, relates to a system and method for detecting abnormalities in intravascular infusion. However, this reference was cited for storing pressure related values and does not overcome any of the deficiencies noted with respect to the Butterfield and Fairchild references. Accordingly, even if combined with the Butterfield and Fairchild references, the combination would not make obvious the claims of the present invention.

In light of the amendments and remarks above, this application ;should be considered in condition for allowance and the case passed to issue. If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated to expedite the prosecution of the application.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

McDERMOTT WILL & EMERY LLP
/John A. Hankins/

John A. Hankins
Registration No. 32,029

4370 La Jolla Village Drive, Suite 700
San Diego, CA 92122
Phone: 858.535.9001 JAH:tms
Facsimile: 858.597.1585
Date: January 15, 2008

Please recognize our Customer No. 41552 as our correspondence address.

SDO 88561-1.080623.0349